

MAR 03 2008

Application No. 10/619,987
Amendment dated March 3, 2008
Reply to Office Action of September 13, 2007**Amendments to the Specification:**

Please replace paragraphs 4-6 on page 5 with the following amended paragraphs:

FIG. 2b illustrates a perspective view of one embodiment of a ligation clip according to the present invention having a base (or support member) and a pressure arm (or clamping arm) for which the applicator of the present invention is designed.

FIG. 2c is a cross section of the ligation clip of FIG. 2b along the line C-C of FIG. 2b.

FIG. 2d is a side view of the ligation clip shown in FIG. 2b with the ligation clip opened.

Please add the following new paragraphs after paragraph 6 (that starts with "Fig. 2d" on page 5:

FIG. 2e is a top view of another embodiment of a ligation clip according to the present invention having a base (or support member) and a pressure arm (or clamping arm).

FIG. 2f is a side view of the ligation clip of FIG. 2e.

FIG. 2g is a top view of the ligation clip of FIGS. 2e and 2f after application to a blood vessel with the pressure arm in a clamped position.

FIG. 2h is a side view of the ligation clip of FIGS. 2e and 2f after application to a blood vessel with the pressure arm in a clamped position.

FIG. 2i is a top view of another embodiment of a ligation clip according to the present invention having a base (or support member) and a pressure arm (or clamping arm).

FIG. 2j is a side view of the ligation clip of FIG. 2i.

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Please replace the paragraph bridging pages 7 and 8 with the following amended paragraphs:

FIG. 2b shows the shape and construction of a typical ligation (or surgical) clip 16 which the device 10 of the present invention is designed to apply during surgical procedures. The ligation clip 16, additional preferred embodiments of which are shown in FIGS. 2e-2h and FIGS. 2i and 2j, is formed generally of a resilient, continuous, wire type material such as titanium or stainless steel, preferably round in cross section. Ligation clip 16 is bent to define and having a base (or support member) 20 and a pressure arm (or clamping arm) 22. Base 20 and pressure arm 22 are connected at their proximate end 24.

The As shown, for example, in FIGS. 2e and 2i, base (or support member) 20 of this particular ligation clip 16 is an elongated U-shaped structure and including a first leg 216 and a second leg 218 joined by a one hundred eighty degree (180°) bend section 220. First leg 216, second leg 218, and bend section 220 form a channel therebetween.

As shown in FIGS. 2b and 2f, for example, in preferred embodiments, base 20 can be straight. In another preferred embodiment, first leg 216 and second leg 218 of base 20, for example, as shown in FIG. 2i, can be curved upwardly to enhance the clamping force distribution characteristics of ligation clip 16. It will be apparent to those skilled in the art that, as in ligation clip 16 of FIGS. 2e-2h, such curvature could be provided alternatively or additionally within pressure arm 22. Where ease of manufacture is a prime objective, each of first leg 216, second leg 218, and base 22 can be straight.

In a preferred embodiment, a proximal free end 224 of ligation clip 16 is joined by a ninety degree (90°) bend section 222 to first leg 216. As shown in FIG. 2f, for example, proximal free end 224 and a segment of bend section 222 is centrally disposed within tension coil 234. As shown in FIGS. 2e and 2i, first leg 216 terminates at its proximal end (away from bend section 220) at bend

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section 222. Furthermore, as shown in FIGS. 2e and 2i, second leg 218 terminates at its proximal end (away from bend section 220) in a loop section 226. Loop section 226 loops inwardly toward pressure arm 22, as shown, for example, in FIGS. 2e and 2i, and resides in a vertical plane perpendicular to the horizontal plane of base 20.

Pressure arm 22 terminates at a tension coil 234, and a distal free end 232 thereof defines the beginning of pressure arm 22. As shown in FIGS. 2b and 2c, pressure arm (or clamping arm) 22-overlies can overlie and extend generally parallel to the base 20 and is be positioned directly above the channel of the "U" formed between the two legs of the U-shaped base 20. Base 20 and the pressure arm 22 are connected at their proximate end 24. In another preferred embodiment, pressure arm 22, as shown in FIGS. 2f and 2h, can include a curved section 236. Curved section 236 of pressure arm 22 moves proximally away from distal free end 232, terminating in tension coil 234. In yet another preferred embodiment, pressure arm 22, as shown in FIG. 2j, can overlie and extend generally parallel to base 20, be positioned directly above the channel of base 20, and contact bend section 220.

The vertical plane established by tension coil 234 is oriented in substantial alignment with the vertical plane of loop section 226, and, accordingly, perpendicular to the horizontal plane of base 20. Loop section 226 and tension coil 234 form the connection between base 20 and pressure arm 22. It will be apparent to those skilled in the art that the orientation of loop section 226 and tension coil 234, and by forming ligation clip 16 of a continuous piece of resilient material, movement of pressure arm 22 will place, as discussed below, pressure arm 22 under tension with respect to base 20. Furthermore, such an orientation will minimize the width and cross-sectional area of ligation clip 16 which is preferred, particularly in laparoscopic surgery.

When ligation clip 16 of FIGS. 2a-2d is in an at rest position, pressure arm 22 overlies and extends generally parallel to base 20 and is positioned directly

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above the channel of base 20. When the ligation clip 16 of FIGS. 2e-2h is in an at rest position, the pressure arm 22 directly overlies the channel between the two legs of the U-shaped base 20. pressure arm 22 is longitudinally aligned with and oriented between first leg 216 and second leg 218 of base 20, but, as shown in FIG. 2f, below the horizontal plane defined by first leg 216 and second leg 218. When ligation clip 16 of FIGS. 2i and 2j is in an at rest position, pressure arm 22 rests in a preloaded condition on the upper surface of base 20 at bend section 220.

HoweverTo open ligation clip 16, the pressure arm 22 can be rotated about the point of connection between base 20 and the pressure arm 22 and the base end 20 at the proximate end 24 to open the ligation clip 16. That is, when when the ligation clip 16 is opened, the pressure arm 22 is pivoted about the connection point between base 20 and pressure arm 22 and base 20. The connection between base 20 and pressure arm 22 at proximate end 24 is a spring type connection (i.e., loop section 226 and tension coil 234); however, that tends to bias the pressure arm 22 back into the "at rest" position as described previously.

Thus, the ligationLigation clip 16 may be opened by separating the pressure arm 22 from the base 20. That separation occurs when the base 20 is held in position and the pressure arm 22 is forced away from the base 20 (as shown, for example, in the illustration shown in FIG. 2d). As shown in FIG. 2d, Pressure pressure is applied to pressure arm 22 to force it to rotate clockwise about the pivotal connection at proximate end 24 between base 20 and pressure arm 22. However, when the pressure is released from pressure arm 22, pressure arm 22 will rotate about the connection point between base 20 and pressure arm 22 and base 20 at proximate end 24 in a counter clockwise position back into the at rest direction (as viewed shown in FIGS. 2a and 2b).

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Looking now at FIGS. 2g and 2h, application of ligation clip 16 of FIGS. 2e-2h to a blood vessel 240 to achieve hemostasis is shown. After ligation clip 16 is placed in the surgical field adjacent to the targeted blood vessel 240, pressure arm 22 is moved upwardly between first leg 216 and second leg 218 to define a gap and space between distal free end 232 and the upper surface of bend section 220. For most uses, a vertical gap of approximately 1.5 mm will be sufficient between distal free end 232 and bend section 220. Ligation clip 16 is then maintained in this position so that blood vessel 240 can be manipulated within the space created between base 20 and pressure arm 22. Pressure arm 22 is then released, trapping vessel 240 within ligation clip 16 as pressure arm 22 moves toward its relaxed position.

The curvature of curved section 236 of pressure arm 22 causes a relatively consistent clamping pressure to be placed over the entire surface of blood vessel 240, thereby achieving effective hemostasis. By placing loop section 226 physically adjacent to, and operatively in series with tension coil 234, a smoother, more consistent application of hemostatic force is obtainable, while increasing the resistance of ligation clip 16 to deformation.

It will be apparent to those skilled in the art that ligation clip 16 is also effective in clamping off ducts connecting various organs, the cystic duct, for example. Accordingly, where the term "vessel" is used herein, it is intended that such reference include all fluid carrying body structures within the surgical field where ligation or clamping is needed.

Where the diameter of the duct or other structure to be clamped is substantially larger than 1.5 mm, a slightly modified method of applying ligation clip 16 is preferred so that the elastic limit of the material used in the construction of ligation clip 16 is not exceeded. In such modified technique, surgical pliers (not shown) of conventional design are first positioned over the area to be

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clamped and the duct or other structure is then compressed to approximately a two wall thickness, or 1.5 mm. The pliers are then removed and ligation clip 16 applied as described above. To minimize the risk of over-compression, the pliers will preferably include a means for limiting closure of its jaws to a minimum spacing of approximately 1.5 mm. The use of this technique on large structures allows ligation clip 16 to be formed with a minimized profile suitable for use in a 5 mm trocar, even if the diameter of the duct or other structure to be clamped, for example, exceeds 5 mm.

To remove or re-position ligation clip 16, pressure arm 22 needs merely to be moved back up into its fully unclamped position, blood vessel 240 and ligation clip 16 manipulated as needed, and then pressure arm 22 is released towards its relaxed position.

Adding a series of ridges, notches, burrs by machining, etching, or other treatment to the clamping surfaces of base 20 and pressure arm 22 can enhance the gripping force of clip 16.

To achieve the objective of minimizing the cross-sectional area of ligation clip 16 of FIGS. 2e-2h, thereby permitting it to be used in laparoscopic surgical procedures, ligation clip 16 is pre-formed into the position substantially as shown on FIGS. 2e and 2f. As such, first leg 216, second leg 218, pressure arm 22, tension coil 234, and loop section 226 are substantially in alignment longitudinally. Furthermore, by extending and preloading pressure arm 22 of ligation clip 16 of FIGS. 2i-2j so that it can assume the position shown in FIG. 2j, the cross-sectional area presented by ligation clip 16 is further minimized, rendering it more adaptable for use in small diameter trocars. Preloading pressure arm 22, of course, helps to maintain ligation clip 16 of FIGS. 2i and 2j in a narrow profile until it is positioned for application.

As shown in FIGS. 2e-2h, in a preferred embodiment of ligation clip 16 adaptable for placement within an endoscopic surgical field through a 5 mm diameter trocar port, the inside diameters of loop section 226 and tension coil

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234 are approximately 3 mm. The length of ligation clip 16, measured from the proximal surface of tension coil 234 to the distal surface of bend section 220 is approximately 12 mm. The width of base 20, measured at the outside surfaces of first leg 216 and second leg 218, is approximately 2.5 mm. Pressure arm 22 is approximately 9 mm from distal free end 232 to its intersection with tension coil 234. In the preferred embodiment of ligation clip 16 of FIGS. 2e-2h, curved section 236 of pressure arm 22 will have a radius of curvature of approximately 25 mm.

A suitable material from which ligation clip 16 can be formed is wrought titanium 6A1-4V ELI alloy wire having a nominal diameter of 0.75 mm, and which meets ASTM Standard F136-92. Ligation clip 16 can also be made of wire having a non-circular cross section, or formed from wire having a combination of circular and non-circular sections. For example, tension coil 234 and/or pressure arm 22 could be stronger if formed from rectangular-shaped wire.